

REMARKS

A. BACKGROUND

The present Amendment is in response to the Office Action mailed June 10, 2009. Claims 2-10 were pending and rejected in view of cited art.¹ Claims 1 and 11-13 were previously canceled, claims 2 and 9 are amended, and new claims 14-19 are added. Claims 2-10 and 14-19 are now pending in view of the above amendments.²

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicant requests that the Examiner carefully review any references discussed below to ensure that Applicant's understanding and discussion of the references, if any, are consistent with the Examiner's understanding.

B. REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

The Office Action rejected claims 3-6 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In response, claim 2 has been amended. In view of this amendment, Applicant respectfully requests withdrawal of the rejection under Section 112.

C. PRIOR ART REJECTIONS

I. REJECTION UNDER 35 U.S.C. § 103

The Office Action rejected claims 2, 3, 5, and 8-10 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,674,231 (*Green*) in view of U.S. Patent No. 6,348,064 (*Kanner*). Claims 4 and 7 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Green* in view of *Kanner* and further in view of U.S. Patent No. 5,593,412 (*Martinez*). Claim 6

¹ Although the prior art status of the cited art is not being challenged at this time, Applicant reserves the right to challenge the prior art status of the cited art at any appropriate time, should the need arise. Accordingly, any arguments and amendments made herein should not be construed as acquiescing to any prior art status of the cited art.

was rejected under 35 U.S.C. § 103(a) as being unpatentable over *Green* in view of *Kanner* and further in view of U.S. Patent No. 5,868,755 (*Kanner2*). Applicant respectfully traverses the Examiner’s rejection for obviousness on the grounds that the references – either individually or in combination – fail to teach or suggest each and every element of the rejected claims.

Claim 2 is amended herein to recite, in part, “the closure element being carried on a carrier assembly slidably disposed on a proximal end of an elongate member” and “advancing the carrier assembly distally along the elongate member from the proximal end towards the distal end of the elongate member, thereby advancing the closure element towards the distal end of the elongate member and causing the skin to separate from the outer surface of the elongate member.” By contrast, neither *Green* nor *Kanner* teaches or suggests a method for delivering a closure element to seal an opening through tissue that incorporates each and every element as is presently claimed in independent claim 2.

Rather, *Green* discloses “a surgical clip 22 . . . releasably supported on a distal end portion of elongated body 20.” (Col. 5, ll. 30-32.) The surgical clip 22 is supported by a “clip support fixture 34 . . . mounted in axial bore 30a adjacent the distal end of support shaft 30,” and is pushed off of the clip support fixture 34 by an elongated pusher tube 42. (Col. 5, ll. 50-52, 62-65.) Applicant respectfully submits that the clip support fixture 34 connected to the distal end of support shaft 30 of *Green* is not the same as “a carrier assembly slidably disposed on a proximal end of an elongate member” as presently claimed in independent claim 2. In addition, pushing the surgical clip 22 off the distal end of the clip support structure 34 with a pusher tube 42 as taught by *Green* is not the same as “advancing the carrier assembly distally along the elongate member from the proximal end towards the distal end of the elongate member, thereby advancing the closure element towards the distal end of the elongate member and causing the skin to separate from the outer surface of the elongate member,” as is presently claimed in independent claim 2. Furthermore, the Office Action has not cited, nor has Applicant found, any portion of *Kanner*, *Martinez*, or *Kanner2* nor that remedies the deficiencies of *Green* with respect to independent claim 2.

Applicant also traverses the Office Action’s rejection for obviousness on the grounds that the Examiner’s combination of *Green* with *Kanner* is improper. The prior art must provide a reason for making a modification to the prior art in order to render a claimed invention obvious.

² Support for the claim amendments and/or new claim(s) can be found throughout the specification and/or drawings as originally filed.

In re Gordon, 221 USPQ 1125, 1127 (Fed. Cir. 1984). "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." M.P.E.P. §2143.01(III) (citing *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990)). "If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious." M.P.E.P. §2143.01(VI) (citing *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959)). Absent proper motivation, a rejection based on a combination of references is unsupported and any rejection based on such a combination must be withdrawn.

Applicant respectfully submits that neither *Green* nor *Kanner* provide sufficient reason for making the proposed modification to the cannula 100 of *Green*. *Green* already provides a mechanism to withdraw "cannula 100 . . . in a proximal direction with respect to elongated body 20 to a retracted position." (Col. 7, ll. 38-41.) Retracting the cannula 100 allows "the arcuate expansion portions 62*b* and 64*b* of locator arms 62 and 64 [to] move into their deployed (unstressed) positions." (Col. 7, ll. 41-43.) Modifying the cannula 100 of *Green* to be expandable or splittable rather than retractable would change the principle of operation taught by *Green* and/or may not be suitable in light of the operation taught by *Green*. The mere fact that the elements of *Green* and *Kanner* could be combined is insufficient to support a *prima facie* case of obviousness. Therefore, there is insufficient reason to modify the cannula 100 of *Green* as proposed in the Office Action.

Furthermore, even if the cited prior art references did provide a reason to modify the cannula 100 of *Green* to incorporate the partially-splittable guide sheath of *Kanner*, the combination does not teach or suggest each and every element of independent claim 2. *Kanner* discloses that "the diameter of the *distal end* of the guide sheath 512 can expand if outward pressure is applied from the inside surface of the guide sheath 512," and that "[m]ore preferably, slits or weakened tear seams . . . are formed in the *distal end* of the guide sheath 512 to allow the diameter of the guide sheath to increase." (Col. 10, ll. 34-40 (emphasis added)). Applicant respectfully submits that the partial expansion of the distal end of the guide sheath 512 as taught by *Kanner*, is not the same as "advancing the carrier assembly distally along the elongate member from the proximal end towards the distal end of the elongate member, thereby advancing the closure element towards the distal end of the elongate member and causing the

skin to separate from the outer surface of the elongate member," as is presently claimed in independent claim 2.

Applicant therefore respectfully submits that the proposed combination of *Green* and *Kanner* does not render independent claim 2, or its corresponding dependent claims, obvious under 35 U.S.C. § 103(a) because the proposed combination is improper and/or fails to teach or suggest each and every element of the present claims. As such, Applicant respectfully requests that the rejections under 35 U.S.C. § 103(a) be withdrawn.

D. CONCLUSION

In view of the foregoing, Applicant respectfully submits that the other rejections to the claims are now moot and do not, therefore, need to be addressed individually at this time. It will be appreciated, however, that this should not be construed as Applicant acquiescing to any of the purported teachings or assertions made in the last action regarding the cited art or the pending application, including any official notice. Instead, Applicant reserves the right to challenge any of the purported teachings or assertions made in the last action at any appropriate time in the future, should the need arise. Furthermore, to the extent that the Examiner has relied on any Official Notice, explicitly or implicitly, Applicant specifically requests that the Examiner provide references supporting the teachings officially noticed, as well as provide the required motivation or suggestion to combine references with the other art of record.

For at least the foregoing reasons, Applicant respectfully submits that the pending claims are neither anticipated by nor made obvious by the art of record. In the event that the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

Dated this 10th day of September, 2009.

Respectfully submitted,

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